UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,443	12/20/2006	Hitoshi Kotani	007123.00001	5782

22907 7590 08/10/2010

BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
08/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,443	KOTANI ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69 and 92-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69 and 92-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks filed on January 27, 2010 have been entered. Claims 69 and 92-98 are pending and under examination.

Response to Amendment

2. The rejection claims 69 and 92 under 35 U.S.C. 102(b) as being anticipated by Kaneda (EP 1170363 A1, filed in IDS of 12/20/06) is withdrawn in view of Applicant's amendment limiting the envelope protein to containing no exogenous nucleic acid, or being empty. Note that if the new matter recited in these claims is removed, this rejection may be reinstated.

Claims Summary and Interpretation

3. Claims 1, 92 and 96 are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that *consists essentially of* a hemagglutinating virus of Japan (HVJ) viral envelope (HVJ-E), wherein IL-12 and IL-16 in dendritic cells are induced or regulatory T cells are inhibited. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. Thus Applicant's composition does not contain any other component that interferes with the ability of HVJ-E to inhibit tumor cell growth.

Claims 93, 94 and 97 are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that *consists of* HVJ-E and a pharmaceutically acceptable carrier, wherein IL-12 and IL-16 in dendritic cells are induced or regulatory T cells are inhibited.

New claims 95 and 98 are drawn to a method of inhibiting tumor cell growth in an animal by administering a composition that *consists essentially of* an empty HVJ-E.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69, 92, 95, 96 and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The claims recite, "wherein the HVJ-E contains no exogenous nucleic acid", and "empty" HVJ-E. These new limitations are not supported in the specification as originally filed. While the concept of a composition consisting of HVJ-E is not new matter, the embodiments that particularly exclude exogenous nucleic acid or require the HVJ-E to be empty, do not appear to have been contemplated at the time of filing.

5. Claims 69 and 92-98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting tumor cell growth in an animal via intratumoral administration of the envelope protein of HVJ, does not reasonably provide enablement for any administration outside of the scope of intratumoral administration. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The breadth of the claims is drawn to a method for inhibiting any type of tumor cell growth *in vivo* by administering a composition consisting essentially of HVJ-E, or consisting of HVJ-E and a carrier, via any route of administration, or in some claims, via injection.

The state of the art, as pointed out by Applicant in the remarks filed January 27, 2010, shows that the HVJ-E protein is capable of inhibiting tumor growth when administered intratumorally. In Kurooka & Kaneda (2007), Fujihara *et al.* (2008) and Kawaguchi *et al.* (2009), (all submitted with the IDS filed 1/27/2010), the mode of administration was intratumoral.

As for guidance from Applicant, the declaration of Toshihiro Nakajuma, filed under 37 CFR 1.132 on July 12, 2010, subcutaneous injection of HVJ-E into a xenograft mouse model for human prostate cancer inhibited tumor growth. The Office has carefully considered the declaration, but it is not persuasive to withdraw the rejection. The Office recognizes that subcutaneous injection of HVJ-E is demonstrated as capable of inhibiting prostate cancer, and that the specification shows that the administration of HVJ-E alone inhibits growth of tumor cells when administered intratumorally (see specification, pages 29 and 30, for example, and also the declaration of Toshihiro Nakajuma, filed under 37 CFR 1.132 on January 27, 2010, demonstrating intratumoral injections of HVJ-E are also shown to inhibit tumor growth). However, this evidence is not commensurate in scope with the claimed invention which is drawn to inhibiting of any type of tumor cell growth via any route of administration, or in some claims, via injection. In the claims that specify administration via injection, the issue remains that

injection encompasses many routes other than the route of subcutaneous injection. One of skill in the art would not reasonably expect any degree of remission from intravenous or oral administration absent evidence of some type of *in vivo* data demonstrating such.

Therefore, in view of the breadth of the claims, the state of the art, and the teachings in the specification, it would require undue experimentation to practice the claimed method of inhibiting tumor cell growth with HJV-E via any route of administration other than intratumoral.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that the rejection is improper because it is not supported by evidence and conclusions based on findings of fact. In response, the Office maintains its position that evidence in this case for which to doubt the efficacy of the claimed invention with regard to the full breadth of the invention, lies in the fact that there is a lack of *in vivo* data commensurate in scope with the claims. The specification shows that the HVJ-E protein is capable of inhibiting tumor growth when administered intratumorally. Applicant submitted references Kurooka & Kaneda (2007), Fujihara *et al.* (2008) and Kawaguchi *et al.* (2009), (all submitted with the IDS filed 1/27/2010), all of which demonstrate efficacy when the mode of administration was intratumoral. The declarations of Toshihiro Nakajuma, show intratumoral injection and subcutaneous injection of HVJ-E into a xenograft mouse model for human prostate cancer. These two methods of administration, intratumoral and subcutaneous injection near the site of the tumor, are not representative of the scope encompassed by the claims. (Note that while subcutaneous injection near the site of a prostate tumor is enabled in view of the declaration, the specification does not have support for subcutaneous injection near the site of a prostate tumor.)

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648